DOCKET NO.: DOVP-1-0901 PATENT

Current Status of the Claims:

This listing of claims will replace the listing of claims in the application:

Listing of Claims:

- 1. (Cancelled).
- 2. (Withdrawn) The method of claim 14 wherein said dosage form is a tablet.
- 3. (Withdrawn) The method of claim 2, wherein the polymer matrix hydroxypropyl methyl cellulose is present in an amount of from about 20% to 40% by weight of the composition.
- 4. (Withdrawn) The method of claim 3 wherein said polymer matrix has a viscosity of from about 100 to about 100,000 cps.
- 5. (Cancelled).
- 6. (Withdrawn) The method of claim 4 wherein the active ingredient is present in the unit dosage form in an amount of about 150-400 mg.
- 7. (Withdrawn) The method of claim 1 wherein the patient is suffering from acute pain and the unit dosage form is administered once or twice a day.
- 8. (Withdrawn) The method of claim 7 where the patient is suffering from minor pain and the unit dosage form is administered once a day.
- 9. (Cancelled).
- 10. (Previously Presented) The unit oral dosage form of claim 16 wherein said composition is in the form of a tablet.
- 11. (Previously Presented) The unit dosage form of claim 16 wherein the hydroxypropyl methyl cellulose polymer matrix is present in an amount of from about 20% to 40% by weight of this composition.

DOCKET NO.: DOVP-1-0901 PATENT

12. (Previously Presented) The unit dosage form of claim 16 wherein said polymer matrix has a viscosity of from about 100 to about 100,000 cps.

- 13. (Previously Presented) The unit dosage form of claim 10 wherein said active ingredient is present in an amount of 200 mg to 400 mg.
- 14. (Withdrawn) A method for reducing pain in a patient in need of said treatment comprising orally administering to said patient in a unit oral dosage form a composition containing from about 25 to 600 mg. of an active ingredient selected from the group consisting of a compound of the formula

and a pharmaceutically acceptable salt thereof,

and from about 15% to 50% by weight, of said composition of a hydroxypropyl methyl cellulose hydrophilic slow release polymer matrix, said unit dosage being orally administered to said patient from once to twice a day.

- 15. (Withdrawn) The method of claim 14 wherein the unit dosage form contains a pharmaceutical acceptable carrier composition containing dibasic calcium phosphate.
- 16. (Previously Presented) A unit oral dosage form comprising a composition containing from about 25 to 600 mg of an active ingredient selected from the group consisting of a compound of the formula

PATENT

and a pharmaceutically acceptable salt thereof,

from about 15% to about 50% of weight of said composition of a hydroxypropyl methyl cellulose hydrophilic slow release polymer matrix.

- 17. (Previously Presented) The unit dosage form of claim 16 wherein said dosage form contains a pharmaceutically carrier composition containing calcium phosphate.
- 18. (Previously Presented) The unit dosage form of claim 17 wherein said carrier is present in an amount of from about 40% to 60% by weight of said composition.
- 19. (Withdrawn) A method for eliciting analgesia in a mammalian subject, comprising:

administering to said subject a therapeutically effective amount of a compound of formula I

or a pharmaceutically acceptable salt thereof, in a daily dosing regimen consisting of one or two doses of the compound of formula I per day, which is effective to elicit analgesia in the subject over approximately a 24 hour period.

- 20. (Withdrawn) The method of claim 19, wherein said therapeutically effective amount of the compound of formula I is between about 200-600 mg.
- 21. (Withdrawn) The method of claim 19, wherein said therapeutically effective amount of the compound of formula I is about 100 mg, about 200 mg, about 400 mg, or about 600 mg.

PATENT

22. (Withdrawn) The method of claim 19, wherein said pharmaceutically acceptable salts are selected from the group consisting of hydrochloride, phosphate, citrate, fumarate, maleate, succinate, pamoate, and sulfate acid-addition salts.

- 23. (Withdrawn) The method of claim 19, wherein said compound of formula I is formulated with a sustained release vehicle in an oral dosage composition which, following administration of the composition to a mammalian subject provides not less than 10% of the compound of formula I released within 15 minutes and not less than 50% of the compound of formula I released within 4 hours and not less than 85% by weight of the compound of formula I released within 12 hours, and effectively elicits analgesia in the subject over approximately a 24 hour period.
- 24. (Withdrawn) The method of claim 23, wherein said sustained release vehicle is a sustained release polymer.
- 25. (Withdrawn) The method of claim 24, wherein said sustained release polymer is a polyacrylic acid polymer or hydroxypropylmethyl cellulose polymer.
- 26. (Previously Presented) A pharmaceutical composition comprising:
 a pre-determined dosage amount of an active ingredient selected from a
 compound of Formula I

and pharmaceutically acceptable salts thereof; and

a sustained release vehicle.

27. (Previously Presented) The composition of claim 26, wherein said predetermined dosage amount of the active ingredient is between about 200-600 mg.

PATENT

28. (Previously Presented) The composition of claim 26, wherein said predetermined dosage amount of the active ingredient is about 100 mg, about 200 mg, about 400 mg, or about 600 mg.

- 29. (Previously Presented) The composition of claim 26, wherein said pharmaceutically acceptable salts are selected from the group consisting of hydrochloride, phosphate, citrate, fumarate, maleate, succinate, pamoate, and sulfate acid-addition salts.
- 30. (Previously Presented) The composition of claim 26, wherein said compound of formula I is formulated with a sustained release vehicle in an oral dosage composition which, following administration of the composition to a mammalian subject provides not less than 10% of the compound of formula I released within 15 minutes and not less than 50% of the compound of formula I released within 4 hours and not less than 85% by weight of the compound of formula I released within 12 hours.
- 31. (Previously Presented) The composition of claim 26, wherein said sustained release vehicle is a sustained release polymer.
- 32. (Previously Presented) The composition of claim 26, wherein said sustained release polymer is a polyacrylic acid polymer or hydroxypropylmethyl cellulose polymer.
- 33. (Previously Presented) A pharmaceutical composition comprising: a pre-determined dosage amount of an active ingredient selected from a compound of Formula I

and pharmaceutically acceptable salts thereof; and

a sustained release vehicle, said composition formulated in an oral dosage form having a sustained release dissolution profile using USP1 apparatus, 20 mesh baskets, 75 rpm, 900 ml phosphate buffer pH 6.8 ± 0.05 , 37° C $\pm 0.05^{\circ}$ C wherein between about 9.2%-17.7% of said compound is released within approximately 0.25 hours.

DOCKET NO.: DOVP-1-0901 PATENT

34. (Previously Presented) The composition of claim 33, wherein said predetermined dosage amount of the active ingredient is between about 200-600 mg.

- 35. (Previously Presented) The composition of claim 33, wherein said sustained release vehicle is a sustained release polymer.
- 36. (Previously Presented) The composition of claim 35, wherein said sustained release polymer is a polyacrylic acid polymer or hydroxypropylmethyl cellulose polymer.
- 37. (Previously Presented) A pharmaceutical composition comprising: a pre-determined dosage amount of an active ingredient selected from a compound of Formula I

and pharmaceutically acceptable salts thereof; and

a sustained release vehicle, said composition formulated in an oral dosage form having a sustained release dissolution profile using USP1 apparatus, 20 mesh baskets, 75 rpm, 900 ml phosphate buffer pH 6.8 ± 0.05 , 37° C $\pm 0.05^{\circ}$ C wherein between about 42.9%-57.4% of said compound is released within approximately 4.0 hours.

- 38. (Previously Presented) The composition of claim 37, wherein said predetermined dosage amount of the active ingredient is between about 200-600 mg.
- 39. (Previously Presented) The composition of claim 37, wherein said sustained release vehicle is a sustained release polymer.
- 40. (Previously Presented) The composition of claim 39, wherein said sustained release polymer is a polyacrylic acid polymer or hydroxypropylmethyl cellulose polymer.
- 41. (Previously Presented) A pharmaceutical composition comprising:
 a pre-determined dosage amount of an active ingredient selected from a
 compound of Formula I

and pharmaceutically acceptable salts thereof; and

a sustained release vehicle, said composition formulated in an oral dosage form having a sustained release dissolution profile using USP1 apparatus, 20 mesh baskets, 75 rpm, 900 ml phosphate buffer pH 6.8 ± 0.05 , 37° C $\pm 0.05^{\circ}$ C wherein between about 65.7%-99.9% of said compound is released within approximately 12.0 hours.

PATENT

- 42. (Previously Presented) The composition of claim 41, wherein said predetermined dosage amount of the active ingredient is between about 200-600 mg.
- 43. (Previously Presented) The composition of claim 41, wherein said sustained release vehicle is a sustained release polymer.
- 44. (Previously Presented) The composition of claim 43, wherein said sustained release polymer is a polyacrylic acid polymer or hydroxypropylmethyl cellulose polymer.
- 45. (Previously Presented) A pharmaceutical composition comprising:
 a pre-determined dosage amount of an active ingredient selected from a
 compound of Formula I

and pharmaceutically acceptable salts thereof; and

a sustained release vehicle, which following administration of the composition to a mammalian subject provides a maximum plasma concentration (Cmax) of said compound in the subject that is less than about 37% of a Cmax provided in a control subject after administration of the same amount of said compound in a rapid release formulation.

- 46. (Previously Presented) The composition of claim 45, wherein said predetermined dosage amount of the active ingredient is between about 200-600 mg.
- 47. (Previously Presented) The composition of claim 45, wherein said sustained release vehicle is a sustained release polymer.
- 48. (Previously Presented) The composition of claim 43, wherein said sustained release polymer is a polyacrylic acid polymer or hydroxypropylmethyl cellulose polymer.
- 49. (Previously Presented) The composition of claim 45, which following administration of the composition to a mammalian subject provides a maximum plasma concentration (Cmax) of said compound in the subject that is between about 27%-37% of

a Cmax provided in a control subject after administration of the same amount of said compound in a rapid release formulation.